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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/843,132	04/25/2001	John P. McKearn	3167/12	8349

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PHARMACIA CORPORATION
GLOBAL PATENT DEPARTMENT
POST OFFICE BOX 1027
ST. LOUIS, MO 63006

EXAMINER	
COOK, REBECCA	

ART UNIT	PAPER NUMBER
1614	

DATE MAILED: 12/22/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/843,132	MCKEARN ET AL.	
	Examiner	Art Unit	
	Rebecca Cook	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 March 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-139* is/are pending in the application.

4a) Of the above claim(s) *6,13,15-39,52,59,61-85,98,105 and 107-131* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5, 7-12, 14, 40-51, 53-58, 60, 86-97, 99-104, 106, 132-139* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *8/14/03* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of irinotecan from the list of DNA topoisomerases and celecoxib from the list of COX-2 inhibitors in the Paper dated March 17, 2003 is acknowledged. Claims 1-5, 7-12, 14, 40-51, 53-58, 60, 86-97, 99-104, 106 and 132-139 are readable thereon. Claims 6, 13, 15-39, 52, 59, 61-85, 98, 105, 107-131 are withdrawn as not reading on the elected combination.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-5, 7-12, 14, 40-51, 53-58, 60, 86-97, 99-104, 106 and 132-139 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treating, does not reasonably provide enablement for preventing or reducing the risk of cancer. The specification does not enable any person skilled in the

art to which it pertains, or with which it is most nearly connected, use the invention commensurate in scope with these claims.

For rejections under 35 U.S.C. 112, first paragraph, the following factors must be considered (In re Wands, 8 USPQ2d 1400, 1404):

1) Nature of invention.

2) State of prior art.

3) Level of ordinary skill in the art.

4) Level of predictability in the art.

5) Amount of direction and guidance provided by the inventor.

6) Existence of working examples.

7) Breadth of claims.

8) Quantity of experimentation needed to make or use the invention based on the content of the disclosure.

See below:

1) Nature of the invention.

The claims are drawn to a method for treating, preventing or reducing the risk of developing a neoplasia using a combination comprising irinotecan and celecoxib.

2) State of the prior art.

Cancer therapy remains highly unpredictable and no examples exist for efficacy of the combination against neoplasia disorders generally or preventing or reducing the risk of developing a neoplasia. Several compounds are used to reduce the risk of developing breast cancer in women who have either had estrogen-receptor positive

breast cancer or are genetically at risk for developing estrogen-receptor positive breast cancer.

3) Level of ordinary skill in the art.

The level of ordinary skill in the art is high. There are a vast number of neoplasia and no examples exist for efficacy of the combination against neoplasia disorders generally or preventing or reducing the risk of developing a neoplasia.

4) Level of predictability in the art.

The art pertaining to the treating, preventing or reducing the risk of developing a neoplasia remains highly unpredictable. No examples exist for efficacy of the combination against neoplasia disorders generally or preventing or reducing the risk of developing a neoplasia.

5) Amount of direction and guidance provided by the inventor.

Applicants contemplate the instant combination, but do not disclose any examples exist for efficacy of the combination against neoplasia disorders generally or preventing or reducing the risk of developing a neoplasia.

6) Existence of working examples.

Applicants' claims are broad, but the specification contains no working examples demonstrating the efficacy of the combination against any neoplasia disorders or preventing or reducing the risk of developing any neoplasia.

7) Breadth of claims.

The claims are extremely broad due to the vast number of possible neoplasia disorders generally included in the recited treatment, prevention or reduction of risk of developing a neoplasia.

8) Quantity of experimentation needed to make or use the invention based on the content of the disclosure.

The skilled artisan would have to screen against an infinite amount of neoplasias in order to determine which ones the combination could be used to treat, prevent or reduce risk of development of specific neoplasia.

Based on the unpredictable nature of the invention and state of the prior art and the extreme breadth of the claims, one skilled in the art could not perform the claimed process without undue experimentation, see In re Armbruster 185 USPQ 152 CCPA 1975.

Claims 93-97, 99-104, 106 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 93-97, 99-104, 106 provide for the "use of", but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claims 93-97, 99-104, 106 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

For the purposes of compact prosecution the claims will be examined as though they were directed to a method of use.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-5, 7-12, 14, 40-51, 53-58, 60, 86-97, 99-104, 106 and 132-139 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 989/25896 and WO 98/40104.

WO 989/25896 discloses that COX-2 inhibitors, including celecoxib are useful to treat cancer (page 3, line 19).

WO 98/40104 discloses that irinotecan (page 5) is useful to treat cancer (page 16).

Furthermore, "[i]t is *prima facie* obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose...[T]he idea of combining them flows logically from their having been individually taught in the prior art." *In re Kerkhoven* 105 USPQ 1069. Therefore, in the absence of a showing of unexpected results, it would be obvious to one of ordinary skill to combine celecoxib and irinotecan to yield the instant

method and composition, since each is individually taught in the prior art to be useful to treat cancer.

Dependent claims differ over the independent claim in reciting specific routes of administration, dosage forms, amounts and that the composition is provided as separate components of a kit. However, once a composition and method of use are known it is within the skill of the artisan to determine said routes of administration, dosage forms, amounts and that the composition is provided as separate components of a kit.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Cook whose telephone number is (703) 308-4724. The examiner can normally be reached on Monday through Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel, can be reached on (703) 308-4725. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

December 15, 2003